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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,361	09/12/2003	David A. Mackiewicz	ENDOS 64949 (4164P)	6762

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
09/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,361	MACKIEWICZ ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17,18,21,32 and 42-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15,17,18,21,32 and 42-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/09 has been entered.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

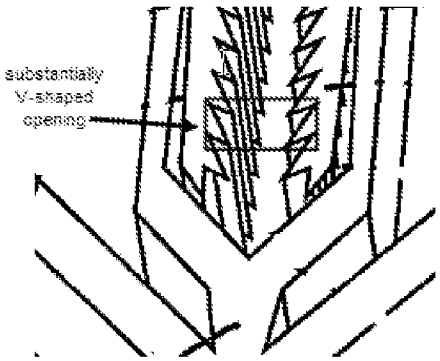
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4, 6, 7, 32, 42, 51, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (USPN 5,741,327) in view of Ehrfeld (DE 197 28 337).

2. Frantzen discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (For example Fig. 11, 64, 67). The device comprises a radiopaque marker (96) attachable within the marker holder. The marker holder includes a pair of projecting fingers, which define an opening (62). The radiopaque marker (94) includes a mounting region (96) that fits within the opening defined by the fingers. The marker is attached to the fingers by a heat weld (Col 7, L64).

3. Frantzen does not disclose that the projecting fingers have a substantially linearly extending contact edge and forms a V-shaped opening or that the radiopaque marker includes a V-shaped mounting region with linearly extending contact edges.

4. However Ehrfeld teaches a connecting configuration (Fig. 4a and 4b) with the holder having projecting fingers (26,27) defining a v-shaped opening (for example 24a and 22a) (note that each pair of corresponding ratchets defines a substantially V-shaped opening as best seen in Fig. 4b and for example shown below) and a prong (21) (equivalent of the claimed marker) including a substantially V-shaped mounting region which fits within the opening of the projecting fingers (Fig. 4b). The connecting fingers are connected at a notched region located between the fingers to allow them to move laterally to accept the prong (compare figures 4a and 4b). The V-shaped opening defines a first angle that is smaller than angle of the prong when the prong is unattached and the V-shaped opening is adapted to enlarge to the angle of the prong when it is placed in the opening. (Compare figures 4a and 4b and note how the inner fingers (27), which define the V-shaped opening, move outward when the prong is inserted, thus increasing the space between the fingers to accommodate the prong and thereby increasing the angle of the V-shaped opening. The mounting region of the prong is clearly larger than the opening defined by the fingers when unattached and the fingers are movable to form a larger opening when attached (as seen in comparing Fig. 4a and 4b). It is clear by the outward movement of the fingers when the prong is inserted that the fingers (holder) applies a force on the sides of the mounting region of the prong.



5. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the connecting technique of Erhfeld into the stent of Frantzen for the purpose of providing a more secure fit. The bias arms combined with the ratchet teeth would provide a strong hold and prevent the two parts for coming apart. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

6. Claims 8-15, 17, 18, 21 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view of Ehrfeld and further in view of Duerig et al (USPN 6,503,271).

7. Frantzen modified by Ehrfeld discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element. However, Duerig discloses a stent with radiopaque markers that are made form a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24). It

would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a micro alloy into the invention of modified Frantzen in order to provide an enhanced material that prevents galvanic corrosion.

8. Regarding claim 10, modified Frantzen by discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 08/06/09 have been fully considered but they are not persuasive. Applicant argues that the combination of Frantzen and Ehrfeld would not result in the claimed structure, but rather would result in a stent having radiopaque markers and locking mechanism for maintaining the stent in an expanded position. Examiner respectfully disagrees. Ehrfeld more broadly discloses a locking mechanism for joining two parts of a device. Frantzen also broadly discloses a locking mechanism for joining two parts of a device. Frantzen teaches the base device of a separate radiopaque marker being secured or locked in place at the end of a stent. As explained in the rejection above, the securing/locking mechanism of Frantzen is being replaced with the securing/locking mechanism of Ehrfeld. A person of ordinary skill has good

reason to pursue the known options within his or her technical grasp if it yields predictable results which in this case is a secure fit for attaching radiopaque markers. .

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
09/09/09